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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,678	12/18/2001	David J. Yang	AH-UTXC:681US	2950
26271	7590	02/24/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,678	Applicant(s) YANG ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 8-22, 24-45, 47-68, 70, 126 and 127 is/are pending in the application.
- 4a) Of the above claim(s) 18-22, 24-45, 47-68 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8-11, 13-17, 126 and 127 is/are rejected.
- 7) ☐ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment filed 11/17/03. Claims 1-3, 5, 8-22, 24-45, 47-68, 70, 126 and 127 are pending. Claims 1-3, 5, 8-17, 126 and 127 read on the elected species and are thus examined.

1. Applicant's arguments with respect to claims 1, 2, 10, 11, 13-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 5, 8, 9, 13-16, 126 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by Delmonte et al. (US 5,989,215).

Delmonte discloses a medical device for the delivery of biochemical solutions, first and second solutions that contains disinfectants or drugs (abstract, column 7, lines 8-27). The biochemical solutions are delivered to localized regions from either a prior art dual container device or one of the devices of Delmonte (example 1 and Figures 1-5). The first biochemical solution of Delmonte is fibrinogen-containing solution and the second biochemical solution is thrombin and calcium containing solution; and the first and second solution may contain disinfectants or drugs (column 7, lines 38-53, column 8, lines 3-29, column 10, lines 22-53 and example 1). Calcium chloride is a cross-linking according to instant dependent claims 13-15. Although, applicant elected cisplatin as the therapeutic agent, the generic claim continues to claim broad therapeutic agent, and the antibiotic of Delmonte is a therapeutic agent. Delmonte

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administers the two solutions from devices disclosed (Figures 1-5). Delmonte thus meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-3, 8-11, 13-17, 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fick (US 5,945,100).

Fick discloses a method of delivering therapeutic reagents to solid tumors (abstracts). The method comprises injecting a polymer solution through a catheter into the regions of the tumor to be treated (abstract). Cisplatin or cisplatin is one of the chemotherapeutic agents to be delivered (column 5, lines 1-3). The delivery vehicle may be polymeric solution that comprises alginate polysaccharide that is ionically cross-linked with a divalent cation such as calcium such that when the delivery vehicle containing the therapeutic cisplatin is injected into the site of treatment it forms a hydrogel (column 7, lines 51, 52 and 59 and column 8, lines 38-44). Regarding claim 15, the forms of calcium recited are the common forms.

Fick teaches the method of the invention except that Fick fails to specifically disclose that the polymer and the cross-linking divalent ions are administered separately from separate containers/compartments. However, since the presence of the cross-linker initiates and leads to cascading of the polymerization process, the cross-linker and the polymer composition should appropriately be administered separately from separate containers/compartments since polymerization happens in situ. Therefore, it would have been obvious to one of ordinary skill

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in the art at the time the invention was made to administer cisplatin in a polymeric vehicle where the polymeric vehicle that is ionically cross-linked with divalent cation at the local site. One having ordinary skill in the art would have been motivated to separately administer the polymeric composition and the cross linking agent from separate containers/compartments with the expectation that polymerization/cross-linkage would not occur in the container but at the localized region.

6. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose poluglutamate or polyaspartate as polymers.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.